UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA *ex rel.* BROOK JACKSON Relators v. VENTAVIA RESEARCH GROUP, LLC, *et al.* Defendants.	)	Case No. 1:21-cv-00008-MJT HONORABLE MICHAEL J. TRUNCALE **ORAL ARGUMENT REQUESTED**

RELATOR BROOK JACKSON'S NOTICE OF MOTION AND RULE 59(e) MOTION TO ALTER OR AMEND ORDER OF DISMISSAL

Under Rule 59 of the Federal Rules of Civil Procedure, Relator Brook Jackson hereby requests the Court alter or amend its Order entered on March 31, 2023, granting Defendants' motions to dismiss the amended complaint in this action. *See* ECF 96. Relator respectfully requests the Court vacate the dismissal and amend the Order to grant leave for Relator to amend under Rule 15, allowing her to proceed on a second amended complaint. The court's order is confusing on the retaliation claim, as it dismissed that count without prejudice, but did not expressly deny leave to amend. The court's denying leave to amend the False Claims Act claims also operates under a false premise: an "inability to plead" a legally sufficient cause when that finding is itself predicated on a misinterpretation of the contract and a misunderstanding of a key fact.

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INTRODUCTION

The court acknowledged that amendment might satisfy a legally sufficient cause in multiple aspects of the court's order, but ultimately denied leave to amend premised on an "inability to plead" sufficient facts as to materiality. However, the court may determine, after amendment, that such facts have been pleaded. This appears particularly true as to the retaliation claim which the court did not dismiss with prejudice.

For example, amendment can allege the following:

1. the intention of the government was to make clinical trial compliance an essential precondition of the contract;
2. the FDA has not accepted any of the allegations of the Brook Jackson complaint as true, continues to trust and believe in Pfizer's lies, and that if the FDA knew the truth, they would immediately revoke authorization just as the Defense Department would demand refund for past payment and cease any future payment;
3. Pfizer did not deliver the promised product nor provide the promised service for a claim of false presentment;
4. Pfizer fraudulently induced the contract by promising to deliver something they could not, and never intended to, deliver;
5. Brook Jackson raised concerns of fraud on the government with her employer and the raising of those concerns precipitated her firing;
6. the details of the invoices submitted and authenticated by Pfizer that relate to each of the claims above;
7. the details of the contract Pfizer submitted and authenticated, and the pertinence thereof to each of the claims above;

8. the evidentiary interrelatedness of the false statements to the fraudulent claims;
9. the essence of the bargain basis for the causes of action of the complaint; and,
10. the direct connection between the fraud Brook Jackson witnessed and the dangerousness, ineffectiveness, and lack of preventative capacity of the Pfizer delivered product.

Plaintiffs should be afforded the opportunity to amend before amendment is presumed futile, in a continually developing case of this consequence.

SUMMARY OF ARGUMENT

In this Rule 59(e) motion, Relator asks the court to vacate the order of dismissal entered on March 31, 2023 (ECF 96) and amend or alter the Order to permit Relator to proceed on a proposed second amended complaint. As demonstrated in the proposed amended pleading (Exhibit A), Relator seeks leave to supplement her allegations and state a claim against Defendants for violation of the False Claims Act on the alternate theory that Pfizer knowingly submitted false or fraudulent data to the FDA, inducing the agency's authorization for the Covid vaccinations. Such fraudulent conduct disqualified Pfizer from eligibility to claim subsequent payments on the contract.

Although brought pursuant to Rule 59(e), Fifth Circuit law requires courts to consider such requests under the liberal standards of Rule 15. Here, as a matter of law, leave to amend would not be futile, as Ms. Jackson in the proposed pleading overcomes the hurdles of falsity and materiality identified in the Court's March 31 order.

Without Rule 59(e) relief, Relator would be denied her day in court based on a technical defect in the operative pleading. Such a result would be manifestly unjust and inconsistent with Rule 15(a)(2), which "evinces a bias in favor of granting leave to amend." *See* Order, at 43

(citing *Smith v. EMC Corp*., 393 F.3d 590, 598 (5th Cir. 2004) (quoting *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 863 (5th Cir. 2003)).

In addition, although the Court dismissed Ms. Jackson's retaliation claims without prejudice, the Order does not expressly grant leave to file a second amended complaint. As demonstrated in the proposed amended pleading, she states viable retaliation claims under the False Claims Act and the Texas Health and Safety Code. Relator therefore respectfully requests leave to file the proposed second amended complaint and pursue her retaliation claims in this Court.

Relator's motion is based on this notice of motion and motion, the memorandum of points and authorities in support of the motion, the proposed second amended complaint, any evidence or argument submitted in the reply or at the hearing of this matter, and the pleadings and exhibits on the docket for this action.

FACTUAL BACKGROUND

As the requested amended complaint makes clear, Pfizer's fraudulent scheme uncovered by Brook Jackson included: first, Pfizer presenting false claims to the government for payment of a product Pfizer never delivered nor ever intended to deliver; second, Pfizer's express certifications to the government the product was delivered according to the contractual terms when it wasn't; third, Pfizer's implied certification to the government the product was delivered according to the rules of clinical trials when it wasn't; and fourth, Pfizer's fraud in the inducement by Pfizer promising to deliver a product they never intended to deliver and knew they couldn't.In sum, Pfizer induced the contract itself by promising to deliver a clinically proven safe, effective, vaccine for the prevention of Covid19 at speed and scale without any other alternative available for Covid19. Pfizer knew they couldn't do that. Indeed, Pfizer knew effective alternatives were available that precluded Pfizer from ever obtaining authorization for their product. Instead, Pfizer delivered a

dangerous, ineffective, gene therapy that didn't prevent anything when Pfizer knew there were effective alternatives available.

Pfizer's product caused more harm than good. Pfizer lied to induce the contract, then lied to induce payment. Pfizer denied the American people the very essence of the bargain. Brook Jackson witnessed this fraud, reported it to her superiors, expressed concern to her employer that this was fraud on the government and when she blew the whistle to the government, she was quickly fired because her employer knew the scale of the fraud on the government she was exposing and wished to silence her instead. The effect of Pfizer's action is the worst fraud on the government in public health history, and the biggest public health debacle of American history. Pfizer, which falsely advertised the product as a safe, effective, vaccine for the prevention of COVID-19 and secretly paid other organizations to lobby for their product to be mandated upon the public as a condition of employment, caused the deaths and disabilities of millions of Americans, while defrauding the American people of billions of dollars.

Pfizer promised a safe, effective, vaccine for the prevention of COVID-19. Pfizer promised they could prove it with strict compliance to the rigorous rules and restrictions of the FDA clinical trial safeguards. Pfizer lied from the inception and kept lying to cover up the first lies to keep the checks flowing. Pfizer knew accurate clinical testing data would reveal those lies. Pfizer knew accurate clinical testing data would reveal a dangerous, ineffective product that was not a vaccine and didn't prevent COVID-19. Pfizer knew accurate clinical trial data would show its product caused death, disability and disease, not prevented it. Pfizer lied, people died, and Pfizer got billions for it. That is what Brook Jackson uncovered. That is what she told her employer she uncovered: fraud upon the government for billions of dollars. So they fired her instead. Their lies continue to work to this day, as the government continues to believe those lies. Pfizer lied. People died. Does Pfizer get to get rich off it?

LEGAL STANDARDS

A motion seeking to vacate an order dismissing a case with prejudice is properly brought under Rule 59(e). See *Rosenzweig*, 332 F.3d at 864 (“Because the Court dismissed the case with

prejudice and entered final judgment, '[u]nder the rule in this Circuit, plaintiff['s] post-dismissal motion must be treated as a motion under Rule 59(e)") (citing *Whitaker v. City of Houston*, 963 F.2d 831, 835 (5th Cir. 1992)). Under ordinary Rule 59(e) standards, a district court may grant relief if an intervening change in controlling law occurs; if new evidence becomes available; or to correct a clear error or law or prevent manifest injustice. See *In re Benjamin Moore & Co.*, 318 F.3d 626, 629 (5th Cir. 2002). Motions under Rule 59(e) "cannot be used to raise arguments which could, and should, have been made before judgment issued." *Elements Chromium L.P. v. Coastal States Petroleum Co.*, 450 F.3d 607, 610 (5th Cir. 2006) (citation omitted).

In this jurisdiction, however, where a party seeks relief under Rule 59(e) to obtain leave to file an amended complaint, the district court's discretion to deny relief is limited by the extreme liberality of Rule 15. See *DeGruy v. Wade*, 586 F. App'x 652, 655-56 (5th Cir. 2014) ("A motion to amend under Rule 15(a) . . . 'permit[s] liberal amendment to facilitate determination of claims on the merits,' imposing serious restrictions on the judge's discretion to deny the motion") (citing *Dussouy v. Gulf Coast Inv. Corp*., 660 F.2d 594, 598 (Former 5th Cir. Nov. 1981)). "Absent a strong, declared reason for the denial, a reviewing court will hold the denial of a Rule 15(a) motion to be an abuse of discretion." Id. Thus, in these limited circumstances, the Fifth Circuit "has held that Rule 15(a)'s limitations on judicial discretion apply to Rule 59(e) motions. Where a district court has entered a judgment on the pleadings and the plaintiff moves under Rule 59(e) to vacate the judgment and amend the complaint, the court should analyze the motion under the Rule 15(a) standard." *Id*. (citing *Rosenzweig*, 332 F.3d at 864; *Dussouy*, 660 F.2d [*656] at 597 n.1). See *Kinder Morgan., Inc. v. Crout*, 814 F. App'x 811, 815 (5th Cir. 2020) ("[W]e review the district court's denial of [a Rule] 59(e) motion for abuse of discretion, in light of the limited discretion of Rule 15(a)"); *United States ex rel. Hebert*

v. Dizney, 295 F. App'x 717, 724 (5th Cir. 2008) ("Relators timely filed a Rule 59(e) motion, and, under these circumstances, the considerations for a motion under Rule 59(e) are the same as those governing a motion under Rule 15(a)"). See also *Kunin v. Saint Luke's Health Sys.*, 2022 U.S. Dist. LEXIS 124581, at *3-6 (W.D. Mo. July 14, 2022) ("[D]istrict courts [in the Eighth Circuit] have considerable discretion to deny a post-judgment motion for leave to amend because such motions are disfavored, but may not ignore the Rule 15(a)(2) considerations that favor affording parties an opportunity to test their claims on the merits") (quoting *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009)). Thus, the Court here is required to apply Rule 15 standards in determining to grant Relator's Rule 59(e) motion.

A party with a technical defect in its pleading that could be cured through amendment should be given leave to amend. "In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. – the leave sought should, as the rules require, be 'freely given.'" *Foman v. Davis*, 371 U.S. 178, 182 (1962).

> The Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits. [*Id*., at 181-82 (quoting *Conley v. Gibson*, 355 U.S. 41, 48 (1957)).]

"All circuits acknowledge that post-judgment leave to amend may be granted if timely requested," as that conclusion "is compelled by the Supreme Court's summary reversal of the denial of such a motion in *Foman*," *Roop* 559 F.3d at 823-24. Indeed, the Rule 59(e) motion presented here is based on the same grounds as the Rule 59(e) motion in *Foman*. See 371 U.S. at

182 ("As appears from the record, the amendment would have done no more than state an alternative theory for recovery").

ARGUMENT

I. Leave to Amend Should Be Granted So Relator Jackson May Pursue a Viable Qui Tam Claim Against Defendants Based on Fraudulent Inducement of FDA Emergency Use Authorization

On March 31, 2023, the Court granted Defendants' motion to dismiss Relator's *qui tam* claims, finding they lacked sufficient factual allegations to state violations of the False Claims Act under either a "false certification" or "false records" theory. The Court held plaintiff failed to allege false statements or a fraudulent course of action under either theory, based on its conclusions that Relator failed to "identify any expressly false certifications of compliance [with regulatory provisions or clinical trial protocol] in Pfizer's invoices seeking payment" or any "specific representations" regarding the vaccines or compliance "in those invoices." Order, at 27. These same conclusions led to the Court's dismissal of Relator's claims under a false records theory, since "there is no liability under the FCA for making or using a false record or statement where the claimant is entitled to the payment." *Id*., at 30.

In opposition to the motions to dismiss, Relator argued that stated facts establish liability under the Act due to fraudulent inducement of FDA's authorization of the vaccinations. *See* Opp., ECF 65, at 10-18. This theory of liability was expressly recognized as potentially viable in the government's Statement of Interest. *See* ECF 70, at 8 ("Consistent with [the 'fraud in the inducement' theory], it may be possible to articulate a viable FCA claim based on materially false or fraudulent statements made to FDA related to a drug or vaccine authorization or approval"). The Court analyzed components of this theory, including "whether liability can attach under the fraudulent inducement theory when a contract was procured through truthful

statements, but a condition of payment – here, FDA authorization – was subsequently obtained through misrepresentations." It did not answer that question, however, as it held Relator failed to plead this theory of liability in the complaint. *See* Order, at 32.

In addition, the Court held Relator could not establish materiality under the Act, given FDA's knowledge of Jackson's allegations, the gravity of the authorization decision, and FDA's actual behavior in re-authorizing Pfizer's vaccines. Order, at 32-38. Although Congress employed an objective definition of materiality, *see* 31 U.S.C. § 3729(b)(4) ("the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"), the Court held that "materiality looks to the effect on the 'likely or actual' behavior of the recipient of the alleged misrepresentation," stating that courts "'should not ignore what actually occurred' when they 'have the benefit of hindsight.'" Order, at 40 (citing *United States ex rel. Harman v. Trinity Indus. Inc*., 872 F.3d 645, 667-68 (5th Cir. 2017)). The Court rejected Relator's claim that misrepresentations went to safety and efficacy of the vaccines – the very essence of the bargain – because Relator failed to plead FDA received fabricated, inaccurate, or misleading data about the safety or efficacy as a result of the alleged misconduct. Order, at 41. Further, the Court found it implausible that Pfizer's data from the Ventavia sites could have caused FDA's approval, in light of the fact that only 3% of the total clinical trial subjects were studied at the Ventavia sites. Order, at 42.

The Court also denied Relator's express pre-dismissal request for leave to amend the complaint if any allegations or claims were found to be deficient. The Court found that any amendment would be futile with respect to the false certification and false records claims pleaded in the amended complaint. Order, at 44. Moreover, the Court held that any proposed

amended complaint "would not alter the conclusion that Defendants' alleged fraud was not material in light of the Government's continued authorization and purchase of the vaccine." *Id.*

In *United States ex rel. Marcus v. Hess*, the Supreme Court recognized that FCA liability can be based on a fraudulent premise that caused the United States to enter into a contract. See 317 U.S. 537, 543-44, 63 S.Ct. 379, 87 L.Ed. 443 (1943)." *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs., Inc.*, 34 F.4th 507, 513 (6th Cir. 2022). Under a fraudulent-inducement theory, Relator must show not only that Defendants' misrepresentations had the potential to induce Government action, but actually did induce (or cause) the Government to act, thus invoking the legal principles of causation, reliance, and inducement. *United States ex rel. Blaum v. Triad Isotopes, Inc.*, 104 F. Supp. 3d 901, 915–16 (N.D. Ill. 2015); See also *United States ex rel. Bid Solve, Inc. v. CWS Mktg. Grp., Inc.*, 567 F. Supp. 3d 59, 75 (D.D.C. 2021), holding a fraudulent inducement claim under the FCA requires relator to plead both but-for and proximate cause, citing *United States ex rel. Cimino v. Int'l Bus. Machs. Corp.*, 3 F.4th 412, 420 (D.C. Cir. 2021).

The fraudulently induced FDA authorization was the but-for cause of the Government's decision to pay; Pfizer even stated it was the *only* condition of payment. Since the sole condition of payment was procured by fraud, it necessarily follows that payment under the contract was fraudulently induced.

Along with this motion, Relator proffers a proposed second amended complaint, curing each of the defects identified in the Court's order of dismissal:

Relator pleads a separate cause of action based on fraudulent inducement of authorization. She makes express allegations that Pfizer abused protocols and produced to FDA false clinical data on safety and efficacy of the vaccines to obtain authorization; that these false

statements were material to the FDA authorization and approval process; that a reasonable, non-compromised, objective agency would have rejected authorization had it known that Pfizer's clinical trial data was false; and, because of Defendants' alleged misconduct, Pfizer was not eligible for subsequent payments on its contracts with the government. *See* Exhibit A, at ¶¶ 283 - 287.

Relator pleads facts showing causation. She alleges that clinical data submitted by Pfizer, including data from subjects at Ventavia sites, and exemplified by the misconduct which Relator learned took place at those sites, caused FDA to authorize the vaccine. She further alleges that a reasonable and objective FDA would have revoked authorization and denied payment had it known about the alleged fraud in the conduct of Pfizer's clinical trials. *Id*., at ¶¶ 326-328.

Relator pleads Defendants' misconduct resulted in FDA's receipt of fabricated, inaccurate and misleading data about the safety and efficacy of the mRNA injections. *See id*. Clinical trial violations identified and reported by Jackson fell into all four of the categories constituting "major protocol deviations," according to Pfizer's Statistical Analysis Plan ("SAP"). Section 5.2 of the SAP lists:

> The following criteria might be considered as major protocol deviations:
>
> (1) Violation of major inclusion or exclusion criteria
>
> (2) Assignment to incorrect vaccine/dose (i.e. actual vaccine/dose taken differs from the scheduled)
>
> (3) Non-Compliance (only one vaccine was administered of P/B vaccines or no vaccine was administered)
>
> (4) Intake of prohibited concomitant medication

Pfizer's own SAP states: "Major protocol deviations are those that are considered to have a significant effect on the treatment efficacy."

Indeed, only 170 clinical trial participants were included in the final efficacy analysis prior to authorization. Had Pfizer followed its own SAP and excluded the participants who fell into the category of major exclusion criteria, the number of participants would have fallen below the minimum number (n=164) required by FDA to constitute a statistically valid data on efficacy.

Moreover, her report of unblinding goes to the heart of safety and efficacy determination. By disclosing who was in the study group and who was in the control group, Pfizer guaranteed the study would be unreliable. Ultimately, Pfizer's unblinding allowed the manufacturer to vaccinate the control group after mere months of study, making it impossible to see how unsafe the mRNA injections are to human health and safety. Subsequent analysis of the trial data demonstrates that Pfizer hid, suppressed and failed to disclose just how unsafe and ineffective the vaccines appeared to be. *Id*., ¶¶ 285-287.

Relator alleges facts which, assumed to be true, plausibly establish that FDA is a compromised government agency, whose actual behavior cannot conclusively establish the lack of materiality at the pleading stage. Said facts include millions of dollars paid by manufacturers to FDA's operating budget and to individuals within FDA hierarchy; gross dereliction of FDA's duty to monitor and report significant adverse events showing clear safety signals; fraudulent approval of the unavailable Comirnaty vaccine while simultaneously extending emergency use authorization for biologic that was actually being injected; and conscious disregard of statements and opinions by scientific experts and its own panelists over negative efficacy and significant harm to Americans. *Id*., at ¶¶ 324-325.

Relator alleges that the problems of false and misleading clinical data was widespread throughout Pfizer's clinical trials. These systemic problems are exemplified by, but are not limited to, what Jackson witnessed at Ventavia. Rather than "hindsight," shocking data analysis of the clinical trial data establishes that Jackson was correct in her allegations that Pfizer knew, but did not care, its vaccines were completely ineffective and unsafe. *Id*., ¶¶ 238-242.

Relator Jackson thus respectfully requests that the Court grant leave to amend, so that she may supplement her previous allegations and to add an express cause of action based on Defendants' fraudulent inducement of FDA authorization. Such leave to amend would not be futile as a matter of law. Applying the reasoning in Foman and the clear Fifth Circuit authority cited above, Jackson is entitled to relief under Rule 15, and her Rule 59(e) motion should be granted.

II. Leave to Amend Should Be Granted So that Relator Jackson May Pursue Viable Retaliation Claims under § 3730(h) and Texas Health and Safety Code

In the Order, the Court also dismissed Relator's retaliation claims, without prejudice. The Court found Relator Jackson complained internally about clinical trial protocol violations and risks to patient safety, but it held – consistent with its ruling on the *qui tam* claims, that these reports did not implicate "fraud against the government." It therefore held that Jackson's activity was not protected by the False Claims Act. Order, at 46-48. In footnote 23, the Court indicated that Jackson "may be able to bring her claim under" a statute other than the False Claims Act. The Court expressed no opinion on whether such a retaliation claim could be successfully prosecuted under a different standard. And the Court did not expressly grant leave to amend.

In the proposed second amended complaint, Relator Jackson overcomes the obstacles noted by the Court with respect to her retaliation claim. First, Relator supplements her first

amended complaint with an express cause of action based upon fraudulent inducement of FDA authorization. This claim, and the allegations supporting it, show the nexus between the Defendants' misconduct with the clinical trials and fraud against the government.

Second, Relator alleges that she had a good faith belief her internal reports of misconduct on the clinical trials to be a "step in furtherance of uncovering fraud, and thus protected" under the False Claims Act. *Guerrero v. Total Renal Care, Inc.*, 2012 U.S. Dist. LEXIS 32615, at *14 (W.D. Tex. Mar. 12, 2012).

Moreover, Jackson adds a separate cause of action under Texas Health and Safety Code § 161.134. This provision prohibits retaliation against employees of any hospital, mental health facility, or treatment facility, which "may not suspend or terminate the employment of or discipline or otherwise discriminate against an employee for reporting to the employee's supervisor, an administrator of the facility, a state regulatory agency, or a law enforcement agency a violation of law, including a violation of this chapter, a rule adopted under this chapter, or a rule of another agency." The statute provides for a private right of action for damages, including actual damages, exemplary damages and reasonable attorneys' fees. The statute creates a rebuttable presumption that an adverse employment action taken within 60 days of a good faith report was for "making a report related to a violation." *See* Sub. (f).

Jackson's claim under the Texas Health and Safety Code would survive Defendants' motions to dismiss. The statute expressly confers protection on any employee who reports on a "violation of this chapter," or any agency rule. Here, Jackson reported major protocol deviations in violation of Federal Acquisition Regulations. Moreover, as shown in the first subchapter of Chapter 161 – § 161.0001 – Texas requires every "health care provider who administers a vaccine is required to record in a medical record under 42 U.S.C. Section 300aa-25, as amended,

including: . . . "any adverse or unexpected events for a vaccine." Jackson's report of Pfizer's failure to report serious adverse injury to one participant's shoulder injury as a result of the vaccine's administration confers protection, and her termination merely days later is presumptively unlawful under the Texas statute.

CONCLUSION

For the foregoing reasons, Relator Brook Jackson requests that the Court alter or amend March 31, 2023, dismissal Order pursuant to Rule 59(e), grant relator's pre-Order request to amend the complaint and, pursuant to Rule 15, allow the filing of the proposed second amended complaint.

Dated: April 28, 2023

Respectfully submitted

/s/ Lexis Anderson

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CERTIFICATE OF SERVICE

I hereby certify that on this 28 day of April 2023 a true and correct copy of the foregoing document was filed electronically in compliance with Local Rule CV-5. All counsel of record consented to electronic service and are being served with a copy of this document through the Court's CM/ECF system under Local Rule CV-5(a)(3)(A).

/s/ Lexis Anderson

Lexis Anderson